



June 7, 2002

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-10

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

Subject: Issuance of a Conditional License for
Avian Influenza Vaccine, Killed Virus, H7 Subtype

To: Biologics Licensees, Permittees, and Applicants
Area Veterinarians in Charge, VS State Veterinarians
Directors, Center for Veterinary Biologics
Veterinary Services Management Team

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Lohmann Animal Health International, Inc., Establishment No. 196, Gainesville, Georgia, for an Avian Influenza Vaccine, Killed Virus, H7 Subtype. The killed virus included in the product is an H7N3 serotype.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstance. The special circumstance addressed here is to have potential availability of an inactivated H7 Subtype Vaccine for use by poultry producers. There is no other licensed vaccine currently available as an aid in the prevention of disease due to Avian Influenza Virus, H7 Subtype.

The conditional license was issued following the acceptance of data supporting purity, a reasonable expectation of efficacy, and field safety. Domestic distribution and use of this product is restricted to use "under the supervision or control of USDA, APHIS, Veterinary Services, as part of an official USDA animal disease control program." The license will expire in 2 years. In accordance with 9 CFR Part 102, progress toward regular licensure must be pursued for reissuance of the conditional license.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



Veterinary Services – Safeguarding Animal Health
An Equal Opportunity Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339